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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,591	08/13/2001	Tomoyasu Sugiyama	14897-080001	7048

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,591	SUGIYAMA ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. For convenience, claim 1 is reproduced below.

1. (Previously presented) A DNA probe consisting of a first region having a sequence which is complementary to a target nucleotide sequence and a second region, following the first region, having a sequence comprising:

a) at least one inosinic acid or derivative thereof; and

b) either or both of at least one labeled nucleotide and at least one labeled nucleotide derivative, wherein the labeled nucleotide or labeled nucleotide derivative is selected from the group consisting of labeled adenylic acid, labeled thymidylic acid, labeled cytidylic acid, labeled guanylic acid, labeled uridylic acid, labeled inosinic acid and derivatives thereof;

and being incapable of hybridizing under stringent conditions to any nucleotide sequence of the target nucleotide sequence, wherein said stringent conditions are 6 x SSC, 0.5% sodium dodecyl sulfate, and 5 x Denhardt's reagent, pH is 7.0 at 68°C.

5. Claim 1 remains rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,124,092 (O'Neil et al.) in view of US Patent 4,917,999 (Byng et al.).

6. O'Neil et al., column 6, disclose the development and use of primers (applicant's probes) that have a first region that is complementary to a target sequence of interest, and a second region that does not hybridize to the target and which serves as a "recovery tag," applicant's second region. The second region is further defined as coupled to the first region "in such a way as to avoid the [second region] interfere with the ability of the [first region] to site-specifically hybridize to the priming site." O'Neil et al., column 6, last paragraph, the recovery tag (applicant's second region) "does not comprise any portion of the template-annealing sequence of he recoverable primer."

7. O'Neil, column 5, disclose various specific binding pairs that may be coupled to or part of the second region. Such members include biotin-avidin.

8. O'Neil et al., column 4, last paragraph, bridging to column 5, discloses that their oligonucleotides may comprise non-naturally occurring backbones, analogs or naturally occurring polynucleotides, including, but not limited to inosine.

9. O'Neil et al., does not state specifically that the sequence of their second region is incapable of hybridizing under stringent conditions, however, it would have been obvious to one of ordinary skill in the art to devise a second region with those very properties as O'Neil et al., do teach that the second region must not interfere with the binding of the first region. In order for there to be any interference, there must be binding taking place, and to not have interference, one would not have binding taking place.

10. Byng et al., Table 1, and in column 3, disclose probes that comprise multiple inosinic residues.

11. Byng et al., column 6, bridging to column 7, disclose a plethora of labels, including labels coupled to modified nucleotides, that the probe may comprise.

12. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the second region of the oligonucleotide of O'Neil et al., such that it comprised multiple inosinic residues as disclosed by Byng et al., and/or inosinic residues in combination with modified nucleotides that comprise a detectable label as such would have afforded the artisan the ability to readily and reproducibly detect similar or related sequences without having to resort to the time, labor and expense of manufacturing additional probes.

13. In view of the well-developed nature of the art, said artisan would have had a most reasonable expectation of success.

14. For the above reasons, and in the absence of convincing evidence to the contrary, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over (US Patent 6,124,092 (O'Neil et al.) in view of U.S. Patent 4,917,999 (Byng et al.).

Response to argument

At page 4, bridging to page 6 of the response received 22 March 2006, hereinafter the response, argument is presented that the introduction of inosinic residues into the second region of O'Neil's oligonucleotide would be counterintuitive as the probe would be less specific.

The above argument has been fully considered and has not been found persuasive as O'Neil et al., does teach using inosinic residues in their oligonucleotide. Further, it is not a requirement that the second region be incapable of hybridizing under any and al conditions, rather, it is only required that it not hybridize under stringent conditions. Such a requirement clearly leaves open the aspect of hybridization occurring under les specific conditions. No convincing evidence has been made of record that the nucleotide sequence of the oligonucleotide of O'Neil et al., lacks such capabilities. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by GIBCO BRL Products & Research Guide (GIBCO).

17. GIBCO lists innumerable biochemical products for sale. At page 15-26 GIBCO lists terminal transferases; at page 17-1 unlabeled nucleotides and unlabeled dNTPs are provided; and at page 17-2, labeled dNTPs are also provided.

18. Such a showing meets a limitation of claim 11. Accordingly, claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by GIBCO BRL Products & Research Guide (GIBCO).

Response to argument

19. At page 6 of the response argument is presented that the products listed for sale by GIBCO do not meet the requirements for claim 11 as hundreds of products are listed, along with the terminal transferase and various labeled and unlabeled nucleotides being available.

20. The above argument has been fully considered and has not been found persuasive as claim 11 uses the term "comprises" to set the metes and bounds of the claim. Accordingly, said kit has been interpreted to comprise an infinite number/variety of components. The fact that other components are also present does not take away from the prior art teaching each limitation of the claimed invention. Further, the aspect that an artisan may well combine the same, or additional reagents in a kit for a different purpose is immaterial as applicant is claiming a compilation of reagents, not a method for using same.

21. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

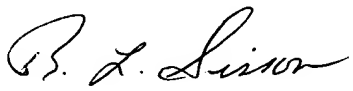
22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
24 May 2006